SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

eSOURCE EDC FOR A COVID TREATMENT TRIAL

OVERVIEW

Signant helped an emerging biopharmaceutical company conduct a phase II trial of a COVID treatment in critically ill patients, optimizing technology to meet the unique challenges of the trial and population.

TRIAL SUMMARY

Study Phase: II

Therapeutic Area: Infectious Disease

Participant Population: Adult

Geographic Scope: 1 country (USA)

Number of Sites: 4

Number of Participants: 30+

Solutions: EDC, with add-on modules for eConsent, eCOA, Randomization and TeleVisits

CHALLENGES

1. **COVID CROSS-CONTAMINATION RISKS ASSOCIATED WITH PAPER DATA COLLECTION**

   The sponsor sought to optimize the study implementation, and limit associated cross-contamination risks, and the need for staff time to transcribe data, by reducing the need to collect and manage data on paper.

2. **RAPID AND STRAIGHTFORWARD CONSENT PROCESS FOR PATIENTS AND LEGALLY AUTHORISED REPRESENTATIVES**

   The sponsor needed to provide a simple way of consenting for hospitalized patients who were able to do so, and a way to facilitate quick and efficient provision of consent by legally authorized representatives remotely.

3. **ENSURING LOW BURDEN, AND EASE OF USE, FOR SITES ASKED TO USE MULTIPLE ECLINICAL SOLUTIONS CONCURRENTLY**

   Because of the number of technology solutions required to optimize the operation of this study, the sponsor sought a solution provider that would ensure a simple, burdensless experience for site staff. This was particular driver in competing for sites during a global pandemic.

SOLUTIONS

1 LEVERAGE DIRECT DATA CAPTURE TO ENABLE ELECTRONIC DATA TO BE COLLECTED AT SOURCE AND REDUCE THE NEED FOR PAPER

Our EDC solution contains the capability to collect data electronically at source. Leveraging its responsive interfaces means that all solutions can be used easily and optimally on a connected mobile device – in this case, enabling capture of patient data directly, at the bedside. Enabling the direct data capture capabilities eliminated the need for transcription of data - made all the more difficult by staff shortages during the global pandemic. eSource data were flagged in the system, ensuring that downstream data management and monitoring activities were adjusted accordingly.

2 ELECTRONIC CONSENT FOR EFFICIENT, PAPERLESS CONSENTING

Leveraging integrated eConsent enabled an efficient approach for patients or their caregivers to provide consent quickly and easily. Legally authorised representatives, where needed, could review the study information and provide consent remotely and rapidly using any web-connected mobile device or personal computer. Patients who were able to provide informed consent themselves, could do so without paper, electronically from the inpatient ward.

3 IMPLEMENT A TRULY UNIFIED TECHNOLOGY PLATFORM

Our foundational EDC solution and its add-on modules for eConsent, eCOA, Randomization and TeleVisits are built using a common, configurable designer and with a single study database. For site users, this provided enhanced simplicity and ease of use. A single access point, and a single set of access credentials per user, meant not needing to remember multiple URLs and username/password combinations. Further, the solution provided efficient, converged guided workflow across the solutions implemented, to simplify the site experience, and reduce training burden.

RESULTS

- Signant implemented the solutions within its fully integrated platform two weeks faster than the proposed timeline, while taking into account all the study needs, including full eSource data capture.

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at **www.signanthealth.com**.